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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 11/25/2003			EXAMINER	
Tanya A. Arenson MEDLEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,345

Applicant(s)

OWYANG, CHUNG

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-12 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 1 March 2002 claiming benefit of U.S. provisional application 60/272,429 filed 1 March 2001. Claims 1-6 and 10-12 are pending.

Election/Restrictions

Applicant's election of Group I in the Paper filed 28 August 2003 is acknowledged. Because applicant did not distinctly and specifically point out alleged errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

All claims directed to nonelected inventions were canceled in the 28 August Paper. Claims 1-6 and 10-12 are under consideration herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4-6 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

The instant claims are directed to a composition comprising an isolated nucleic acid encoding a polypeptide that binds to Orphanin FQ, wherein said nucleic comprises a nucleic acid sequence capable of hybridizing under conditions of low stringency, or having at least 85% or 90% identity to a nucleic acid sequence set forth in the disclosure as SEQ ID NO: 9, 10, 12, 14, 16, 18, 19, 20, or 21, or encoding a polypeptide that is at least 95% identical to the polypeptides set forth as SEQ ID NO: 11, 13, 15, 17 and 23. The specification sets forth conditions of low stringency at page 16 as equivalent to binding or hybridization at 42 °C in a solution consisting of 5X SSPE, 0.1% SDS, 5X Denhardt’s reagent, 5g BSA, and 100 g/ml denatured salmon sperm DNA followed by washing in 5X SSPE, 0.1% SDS at 42 °C. Given these hybridization conditions or a homology set forth, the claims encompass a genus of nucleic acid molecules of widely divergent structure.

The Guidelines for Written Description state: “when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus” (Federal Register, Vol. 66, No. 4, Column 3, page 1106). “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or

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by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; MPEP §2163(3)(a)(ii).

The art discloses several nucleic acid molecules which fall within the structural limitations of the claims and have the function of binding Orphanin FQ (see Claim Rejections-35 U.S.C. §102 below). However, all of the nucleic acids disclosed in the art encode polypeptides having closely related structure. The art does not teach that binding of Orphanin FQ is a characteristic of structurally divergent polypeptides and does not disclose the structural characteristics that would confer on any protein the function of binding Orphanin FQ. Thus, a genus of nucleic acids having widely divergent structure and possessing the ability to bind Orphanin FQ is not conventional in the art.

The teachings of the instant specification do not cure the deficiencies of the art such that the skilled artisan would be able to envision the genus of claimed nucleic acids. With regard to actual reduction to practice, the instant disclosure describes a series of splice variants of the Orphanin FQ receptor that are naturally expressed in rat tissues, which meet the structural limitations of the claims but are not demonstrated to have the function of binding Orphanin FQ. Thus, although several structural variants are disclosed, the specification fails to correlate the structure with function and, therefore, fails to convey the structural requirements of a polypeptide that binds to Orphanin FQ. In the absence of a disclosed nexus between structure and function, the skilled artisan cannot possibly envision nucleic acid molecules encoding

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polypeptides having the ability to bind Orphanin FQ other than those specifically disclosed in the art and specification.

Although the specification describes assays that might allow the skilled artisan to identify the claimed nucleic acids by empirical experimentation, an adequate written description of a nucleic acid requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the nucleic acid itself. It is not sufficient to define nucleic acid solely by its principal biological property (i.e., it encodes a polypeptide that binds Orphanin FQ) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any nucleic acid with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all nucleic acids that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acids encoding polypeptides that bind Orphanin FQ. Therefore, only the described nucleic acids set forth as SEQ ID NO: 9, 10, 12, 14, 16, 18, 19, 20 and 21 or encoding SEQ ID NO: 11, 13, 15, 17 and 23 meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1, 3, 4-6 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid set forth as SEQ ID NO: 9, 10, 12, 14, 16, 18, 19, 20 or 21 and a nucleic acid encoding a polypeptide set forth as SEQ ID NO: 11, 13, 15, 17 or 23, does not reasonably provide enablement for the broad genus of nucleic acids capable of hybridizing under conditions of low stringency, or having at least 85% or 90% identity to a nucleic acid sequence set forth in the disclosure as SEQ ID NO: 9, 10, 12, 14, 16, 18, 19, 20, or 21, or encoding a polypeptide that is at least 95% identical to the polypeptides set forth as SEQ ID NO: 11, 13, 15, 17 and 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims: The scope of the claims is described hereinabove. To summarize, the claims encompass a genus of nucleic acids having broadly divergent structure wherein said nucleic acids are limited to encoding a polypeptide that binds Orphanin FQ.

State of the prior art and level of predictability in the art: As described herein above, the art discloses several nucleic acid molecules that encode polypeptides that bind Orphanin FQ wherein the nucleic acid molecules meet the structural limitations of the claims. However, the art is silent with regard to the structural requirements for binding Orphanin FQ and does not describe polypeptides of widely divergent structure capable of binding Orphanin FQ such that those features common to polypeptides capable of binding Orphanin FQ would be readily apparent to the skilled artisan. Thus, the skilled artisan seeking to make the full scope of the claimed invention would not be able to identify nucleic acids encompassed by the claims without having to make each nucleic acid encompassed the structural limitations set forth and then testing each nucleic acid for the function of encoding a polypeptide that binds Orphanin FQ.

Amount of direction provided by the inventor and existence of working examples: Other than describing a series of naturally occurring nucleic acids encoding polypeptides that are structurally related to proteins capable of binding Orphanin FQ (*Id.*), the instant disclosure does not provide any guidance that would enable the skilled artisan to identify nucleic acids encoding polypeptides that bind to Orphanin FQ beyond what was available in the art at the time of filing. Although the polypeptides encoded by the nucleic acids disclosed in the instant application are putative Orphanin FQ binding proteins because they are encoded by the same gene as a known Orphanin FQ binding protein, binding of Orphanin FQ by the encoded polypeptides is not

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demonstrated. Thus, the teachings of the specification do not set forth the structural requirements of Orphanin FQ binding in any more detail than does the prior art.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is high, making the instant claimed invention commensurate with its full scope would require undue experimentation. As the teachings of the art and specification fail to convey the relevant identifying characteristics of a nucleic acid encoding a polypeptide capable of binding Orphanin FQ, the skilled artisan would not be able to make the claimed invention without having to test each and every nucleic acid having the structural limitations set forth for the ability to encode a protein that binds Orphanin FQ.

Although the presence of inoperative embodiments within the scope of the claim does not necessarily render a claim non-enabled (see *Atlas Powder Co. v. E.I. du Pont de Nemours & Co* (224 USPQ 409, 414; hereinafter *Atlas*). *Atlas* also provides, “[o]f course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid” (page 414). Given the breadth of the structural limitations set forth in the claims, the nucleic acids encompassed thereby would certainly contain a significant number of inoperative embodiments. Furthermore, the failure of the art and specification to describe Orphanin binding proteins such that nexus of structure with the function of binding to Orphanin FQ would be readily apparent to the skilled artisan, determination of which embodiments that were conceived, but not yet made, would be inoperative or operative would clearly require undue

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experimentation. Therefore, the disclosure is not enabling for the full scope of the claimed subject matter.

Claims 1-4, 6 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid, and an isolated cell comprising the vector of claim 5, to the extent that the nucleic acid and vector comprises a sequence indicated above to be adequately described and enabled, does not reasonably provide enablement for any composition comprising the isolated nucleic acid, or a cell comprising the vector of claim 5 wherein the cell is *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Nature of the invention and breadth of the claims: The invention of claims 1-4 and 10-12 is directed to a composition comprising an isolated nucleic acid sequence encoding a polypeptide that binds to Orphanin FQ. As the term "composition" is not defined in the specification, the claimed composition is understood, according to its broadest reasonable interpretation, to encompass any composition of matter wherein an isolated nucleic acid according to the claims is present. Further, as the specification specifically contemplates transgenic animals comprising the nucleic acid (see especially the paragraph bridging pages 25-26), the claimed composition is understood to encompass a transgenic animal. Likewise, the cited statement at pages 25-26 indicates, "host cells may be located in a transgenic animal." Thus, the claimed host cell also encompasses a host cell wherein the host cell is located in a transgenic animal

Level of predictability and state of the prior art: When considering the predictability of this invention, one has to remember that many of the phenotypes examined in transgenic and knockout models are influenced by the genetic background in which they are studied and the effect of allelic variation and the interaction between the allelic variants (pg.1425, paragraph 1 in Sigmund, C.D. (2000) *Arterioscler Thromb Vasc Biol.* 20:1425-1429). Doetchman (1999) *Lab. Animal Sci.* 49:137-143 teaches, “[o]ne often hears the comment that genetically engineered mice...are not useful because they frequently do not yield the expected phenotype, or they don’t seem to have any phenotype. These expectations are often based on years of work, and in some instances, thousands of publications of mostly in vitro studies” (page 137, paragraph 1). Doetchman goes on to teach, “it has become clear that genetic background plays an important role in the susceptibility of mice to many disorders. Therefore, the phenotypes of knockout mouse strains will also have genetic background dependencies” (page 140, column 2, third full paragraph) and “[a]pparent lack of phenotype more likely reflects or inability to ask the right questions, or our lack of tools to answer them” page 142, first paragraph. These teachings point out that the phenotype arising from any given mutation or genetic manipulation of a transgenic mouse is highly unpredictable and in some cases requires empirical experimentation to uncover. Further, transgene expression and the physiological consequences of transgene products are not always accurately predicted in transgenic mouse studies (pg.62, paragraph 1, lines 7-9 in Wall, R.J. (1996) *Theriogenology* 45:57-68). Still further, the particular genetic elements required for optimal expression varies from species to species. Our lack of understanding of essential genetic control elements makes it difficult to design transgenes with predictable behavior (Wall, 1996). Therefore, given no more than the functional characteristics of a gene as they are determined

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under *in vitro* conditions, the skilled artisan is unable to predict what phenotypic characteristics would be comprised by a transgenic animal expressing the gene.

With regard to an animal transgenic for an Orphanin FQ receptor in particular, a review of the relevant art published at the time the instant application was filed indicates that the physiological role of Orphanin FQ and its receptor was unclear at the time of filing. In the section entitled “*D. Reconciling the Literature*” Mogil *et al.* (2001) *Pharmacol. Rev.* 53:381-415 teaches, “[t]he preceding description of OFQ/N effects on nociceptive phenomena at the supraspinal, spinal, and peripheral levels...illustrate the considerable uncertainty that still surrounds the simplest of questions: What are the actions of OFQ/N when injected?” (page 395, column 1). Thus, these teachings indicate that at the time of filing the art was not developed to the point that one of skill in the art that one of skill in the art could even reliably predict the effect of Orphanin FQ administration on a wild-type animal. Given this underdeveloped state, the skilled artisan clearly would not be able to predict what effect ectopic or overexpression of an Orphanin FQ receptor would have on the phenotype of a transgenic animal.

Amount of direction provided by the inventor and existence of working examples: The instant specification discloses a series of naturally occurring nucleic acids encoding polypeptides that are structurally related to proteins capable of binding Orphanin FQ (*Id.*). However, there is no description of a transgenic animal comprising the disclosed nucleic acids beyond a statement that the claimed host cell can be located in a transgenic animal. The teachings clearly fail to address the unpredictability of phenotype that is a general feature of transgenic animals and particularly pronounced in the instant case given the underdeveloped state of the art.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is high, given the art-recognized unpredictability of the phenotype arising from expression of any given gene in a transgenic animal and the particularly high degree of unpredictability of the phenotype arising from expression of an Orphanin FQ binding protein, the skilled artisan would have to resort to blind trial and error experimentation in order to uncover a useful phenotype in the transgenic animal. Therefore, in the absence of specific teachings from the art, using animals comprising an Orphanin FQ transgene would require undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Pan *et al.* (1998) *FEBS Lett.* 435:65-68, Chen *et al.* (1994) *FEBS Lett.* 147 :279-283, Pan *et al.* (1995) *Mol. Pharmacol.* 47:1180-1188 (hereinafter, Pan *et al.* '95), Bunzow *et al.* (1994) *FEBS Lett.* 347 :284-288, Wick *et al.* (1994) *Brain Res. Mol. Brain Res.* 27:37-44, Grandy *et al.* (U.S. Patent No. 5,821,067), or Eppler *et al.* (U.S. Patent No. 5,866,324).

Pan *et al.* discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 90% identical to the instant SEQ ID NO: 12 and 17, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (the sequence of Pan *et al.* is disclosed in the public nucleic acid databases as AF043276.1 GI:3769423). Thus, the nucleic acid of Pan *et al.* meets the limitations of claims 1, 3, 4 and 10. Pan *et al.* isolates the nucleic acid from a library wherein the nucleic acids in the library are comprised within a vector and a host cell (see especially section 2.2 “*cDNA library screening*”). Thus, Pan *et al.* also teaches the limitations of claims 5 and 6.

Chen *et al.* discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12 and 17 and greater than 90% identical to the instant SEQ ID NO: 14, 19, 16 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (the sequence of Chen *et al.* is disclosed in the public nucleic acid databases as L28144.1 GI:496219). Thus, the nucleic acid of Chen *et al.* meets the limitations of claims 1, 3, 4 and 10. Chen *et al.* further teaches an expression vector comprising the nucleic acid and a host cell (i.e., COS-7 cell line) comprising said vector (see especially section 2.2 “*Transient expression in COS-7 cells*”). Thus, Chen *et al.* also teaches the limitations of claims 5 and 6.

Pan *et al.* '95 discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12, 16, 17 and 20, and greater than 90%

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identical to the instant SEQ ID NO: 14 and 19, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (the sequence of Pan *et al.* '95 is disclosed in the public nucleic acid databases as U09421.1 GI:551484). Thus, the nucleic acid of Pan *et al.* '95 meets the limitations of claims 1, 3, 4 and 10. Pan *et al.* '95 further teaches an expression vector comprising the nucleic acid and a host cell (i.e., COS-7 cell line) comprising said vector (see especially the right column on page 1181). Thus, Pan *et al.* '95 also teaches the limitations of claims 5 and 6.

Bunzow *et al.* discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12, 16 and 17 and greater than 90% identical to the instant SEQ ID NO: 14, 19 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (see especially Figure 1 and the caption thereto). Thus, the nucleic acid of Bunzow *et al.* meets the limitations of claims 1, 3, 4 and 10. Bunzow *et al.* further teaches an expression vector comprising the nucleic acid and a host cell (i.e., COS-1 and COS-7 cell line) comprising said vector (see especially the second full paragraph in the right column on page 284). Thus, Bunzow *et al.* also teaches the limitations of claims 5 and 6.

Wick *et al.* discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 90% identical to the instant SEQ ID NO: 19 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (see especially Figure 1 and the caption thereto). Thus, the nucleic acid of Wick *et al.* meets the limitations of claims 1, 3, 4 and

10. Wick *et al.* further teaches an expression vector comprising the nucleic acid and a host cell (i.e., COS-7 cell line) comprising said vector (see especially section 2.7 “*Expression in COS-7 cells and binding analysis*” on page 39). Thus, Wick *et al.* also teaches the limitations of claims 5 and 6.

Grandy *et al.* discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12, 16 and 17, and greater than 90% identical to the instant SEQ ID NO: 14, 19 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (see the sequence set forth as SEQ ID NO: 3). Thus, the nucleic acid of Grandy *et al.* meets the limitations of claims 1, 3, 4 and 10. Grandy *et al.* further teaches an expression vector comprising the nucleic acid and a host cell comprising said vector (see especially Example 3). Thus, Grandy *et al.* also teaches the limitations of claims 5 and 6.

Eppler *et al.* discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12, 14, 16 and 17 and greater than 90% identical to the instant SEQ ID NO: 19 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (see the sequence set forth as SEQ ID NO: 1). Thus, the nucleic acid of Eppler *et al.* meets the limitations of claims 1, 3, 4 and 10. Eppler *et al.* further teaches an expression vector comprising the nucleic acid and a host cell (i.e., COS-7 cell line) comprising said vector (see especially Example 3). Thus, Eppler *et al.* also teaches the limitations of claims 5 and 6.

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The nucleic acids and host cells of the prior art are the same as those claimed in the instant application; therefore, the claims are anticipated by the art.

Claims 1, 3, 4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI Entrez Nucleotide Database Accession Number U05239.1 (GI:45183), published 1994.

Accession number U05239.1 discloses an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12 and 17 and greater than 90% identical to the instant SEQ ID NO: 14, 19, 16 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17. Thus, the nucleic acid of Accession Number U05239.1 meets the limitations of claims 1, 3, 4 and 10.

Claims 1, 3-6 and 10 are rejected under 35 U.S.C. 102(c) as being anticipated by Yu (U.S. Patent No. 6,103,492).

Yu discloses a composition comprising an isolated nucleic acid sequence wherein said nucleic acid sequence encodes a polypeptide that binds to Orphanin FQ and is greater than 85% identical to the instant SEQ ID NO: 12 and 17 and greater than 90% identical to the instant SEQ ID NO: 14, 16, 19 and 20, wherein the polypeptide encoded thereby is greater than 95% identical to the instant SEQ ID NO: 15 and 17 (see the sequence set forth as SEQ ID NO: 16). Thus, the nucleic acid of Yu meets the limitations of claims 1, 3, 4 and 10. Yu further teaches an expression vector comprising the nucleic acid and a host cell (i.e., COS-7 cell line) comprising said vector (see especially column 77). Thus, Yu also teaches the limitations of claims 5 and 6.

The nucleic acids and host cells taught by Yu are the same as those claimed in the instant application; therefore, the claims are anticipated by the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DMS


JAMES KETTER
PRIMARY EXAMINER